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| APPLICATION NO.        | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|------------------------|-------------|----------------------|---------------------|------------------|
| 10/014,279             | 12/11/2001  | Johnny Paul Speir    | 140-067a            | 2332             |
| 27776                  | 7590        | 12/21/2007           | EXAMINER            |                  |
| WARD & OLIVO           |             |                      | LIN, JERRY          |                  |
| SUITE 300              |             |                      |                     |                  |
| 382 SPRINGFIELD AVENUE |             |                      | ART UNIT            | PAPER NUMBER     |
| SUMMIT, NJ 07901       |             |                      | 1631                |                  |
|                        |             |                      |                     |                  |
|                        |             |                      | MAIL DATE           | DELIVERY MODE    |
|                        |             |                      | 12/21/2007          | PAPER            |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/014,279             | SPEIR, JOHNNY PAUL  |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Jerry Lin              | 1631                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 04 October 2007.  
 2a) This action is FINAL.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 30-33 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 30-33 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 28 June 2002 is/are: a) accepted or b) objected to by the Examiner.  
     Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
     Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

### **DETAILED ACTION**

1. Applicants' arguments, filed October 4, 2007, have been fully considered and they are deemed to be persuasive in part. However, in light of recently discovered prior art, the following rejections are newly applied. They constitute the complete set presently being applied to the instant application.

### **Status of the Claims**

Claims 30-33 are under examination.

#### ***Claim Rejections - 35 USC § 112, 2<sup>nd</sup> Paragraph***

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 30-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 30 also recites "an empirical formula of said sample." An empirical formula usually refers to a single chemical compound or molecule. However, the sample is limited in line 4 to contain several metabolic products, such metabolic products encompass chemical compounds. Thus, it is unclear how a sample comprising multiple chemical compounds could have a single empirical formula.

Claim 30 also recites "each species." It is unclear to what in the sample is the species referring.

Claims 31-33 are rejected for depending from claim 30.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 30-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Dasseux et al. (US 2002/0019023 A1) in view of Ji et al. (J. Chem. Soc., Perkins Trans. 2 (2001) pages 585-591) in view of Mighell et al. (Journal of Research of the National Institute of Standards and Technology (1996) Volume 101, number 3, Pages 273-280).

The instant claims are drawn to a method of analyzing a drug-dosed sample using a Mass Spectrometer which includes ionizing a drug-dosed sample, introducing the ions into an analysis region, monitoring the ions, detecting changes, determining the molecular weight of each species of molecules, identifying species by comparing the empirical formula to a database.

Regarding claims 30, 32, and 33, Dasseux et al. disclose a method of analyzing a drug-dosed sample that includes ionizing a drug-dosed sample comprising metabolic products (page 12, paragraph 0117- page 13, paragraph 0127; page 10, paragraphs 0090-0091); introducing said ions to the analysis region of a mass spectrometer such as a FTMS (page 3, paragraph 0022; page 13, paragraph 0132-page 14, paragraph

0136); continuously monitoring the ions and detecting changes to the sample (page 15, paragraph 0153); determining the molecular weight of each species present in a sample (page 17, paragraphs 0169-178). Furthermore, Dasseux et al. teach using electrospray ionization (page 13, paragraph 0125) as well as chemical ionization (page 12, paragraph 0118). Electrospray ionization and chemical ionization are forms of Atmospheric Pressure Ionization as in claim 33.

However, Dasseux et al. do not explicitly teach determining the empirical formula from the molecular weight or identifying each species by comparing the empirical formula to a database of formulas for known molecules.

Regarding claim 30, Ji et al. teach using FTMS to determine the molecular weight of a species and using the molecular weight to determine the empirical formula (verifying a empirical formula would require determining the empirical formula from the molecular weight to compare to the predicted empirical formula) (page 590).

Also regarding claims 30 and 31, Mighell et al. disclose a database that is searchable by querying the empirical formula (page 278, section 4.1) and are updated with new scientific information (page 273, right column).

It would have been obvious to one of ordinary skill in the art at the time of the invention, to combine the teachings of Dasseux et al., Ji et al., and Mighell et al. for the benefit of obtaining additional data related to the identified chemical species. The databases of Mighell et al. are comprehensive and are cross-referenced with other databases (page 274, left column). These other databases provide additional data which may be used as a basis for scientific research as an aid to scientific research

(page 273, left column). One of the ways to search Mighell et al.'s database is to use the empirical formula (page 278, section 4.1). Thus, after obtaining data from the method of Dasseux et al., one of ordinary skill in the art seeking to search Mighell et al.'s database would have been motivated to determine the empirical formula from the data of Dasseux et al. Ji et al. teach a method of determining the empirical formula from FTMS data such as the data in Dasseux et al. Thus, one of ordinary skill in the art would have been motivated to combine the methods of Dasseux et al., Ji et al., and Mighell et al. to find additional data for scientific research.

Response to Arguments

4. Applicants have responded previously that Dasseux et al. do not teach "continuously monitoring said ions." The Examiner disagrees. The Examiner's interpretation of the limitation of "continuously monitoring said ions" is monitoring the ions uninterrupted for a period of time. Dasseux et al. teach processing each sample uninterrupted for a period of time. Applicants point page 15, paragraph 0153, and state that since Dasseux et al. run multiple samples, the monitoring is not continuous. However, the instant claims are drawn to running one sample continuously, not multiple samples. Dasseux et al. do teach monitoring a single sample continuously. In other words, Dasseux et al. do not interrupt the FTMS process when analyzing the sample in a mass spectrometer.

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***Withdrawn Rejections***

5. Applicant's arguments, filed October 4, 2007, with respect to the rejection made under 35 U.S.C. §102 as being anticipated by Dasseux et al. have been fully considered and are persuasive. As stated above, Dasseux et al. do not explicitly teach determining the empirical formula from the molecular weight or identifying each species by comparing the empirical formula to a database of formulas for known molecules. This rejection of has been withdrawn.

***Conclusion***

No claim is allowed.

***Contact Information***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Lin whose telephone number is (571) 272-2561. The examiner can normally be reached on 10:00-6:30, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie A. Moran can be reached on (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JL/

/Marjorie A. Moran/  
SPE, AU 1631  
12/19/2007